Journal of Engineering Science *Vol. XXXIII, no. 2 (2026), pp. 61 - 70*
Fascicle *Electronics and Computer Science* *ISSN 2587-3474*
Topic *Biomedical Engineering* *eISSN 2587-3482*

https://doi.org/10.52326/jes.utm.2026.33(2).05
UDC 615.47:006.83:620.1

OPTIMIZATION OF THE CONFORMITY ASSESSMENT PROCESS FOR MEDICAL DEVICES UNDER CONDITIONS ENSURING THE EVALUATION OF SAFETY AND PERFORMANCE PARAMETERS

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Received: 04.05.2026
Accepted: 05.12.2026

Abstract. Periodic verification through examinations and laboratory testing represents a technical operation that can ensure an adequate level of performance and safety of medical devices. This verification ensures the assessment of general safety, electrical safety, functionality, alarm control, and, most importantly, the performance parameters of medical devices. In order to establish a service system intended for the periodic conformity assessment of medical devices, it was necessary to identify new methodological approaches. This methodology is based on the cost–effectiveness ratio, ensuring the application of a minimum set of non-destructive methods in accordance with standards, while guaranteeing an appropriate level of performance and safety of medical devices.

Keywords: *medical devices, periodic conformity assessment, periodic inspection, non-destructive testing, standards, safety, performance, reliability, efficiency, quality.*

Rezumat. Verificarea periodică prin examinări și încercări de laborator reprezintă operațiunea tehnică ce poate garanta nivelul adecvat al performanțelor și siguranței dispozitivelor medicale. Această verificare asigură evaluarea securității generale, a securității electrice, a funcționalității, a controlului alarmelor și, cel mai important, controlul parametrilor de performanță a dispozitivelor medicale. Pentru a institui un sistem de servicii destinat evaluării periodice a conformității dispozitivelor medicale, a fost necesară identificarea unei noi metodologii. Metodologie, care are la bază raportul cost-eficiență, prin care se asigură îndeplinirea setului minim de metode nedistructive conform standardelor, cu garantarea nivelului corespunzător de performanță și securitate al dispozitivelor medicale.

Cuvinte-cheie: *dispozitive medicale, evaluarea periodică a conformității, verificare periodică, metode nedistructive, standarde, securitate, performanță, siguranță, eficiență, calitate.*

1. Introduction

In order to ensure the functionality and practical applicability of the system for periodic conformity assessment of medical devices, based on the established regulatory framework, it was necessary to develop specific procedures for the periodic verification of medical devices in accordance with the Nomenclature approved by the Annex to Government Decision No. 966/2017 "On the approval of the Regulation regarding the periodic verification of medical devices placed into service and in use" [1, 2, 3].

In this context, it was necessary to determine a methodology for selecting non-destructive testing methods from applicable standards, based on a cost–efficiency ratio, in order to ensure an appropriate level of performance and safety of medical devices.

Considering that the verification interval is 24 months, it was also necessary to take into account the allocation of financial resources for periodic verification activities, in order to ensure the continuity of this process by medical institutions. Furthermore, consideration was given to the time required to perform periodic verification, in order to avoid prolonged downtime of medical devices, as well as to the human, material, and financial resources required for this purpose.

Based on these considerations, the requirements of standards applicable to medical devices at the manufacturing stage were researched and analyzed, with the aim of identifying the methods within those standards that would form the basis for the specific verification procedures.

Standards include both destructive and non-destructive methods, which are fully applied at the manufacturing stage, particularly during the conformity assessment. However, for the periodic verification medical devices that have already been placed into service and are in use, and which have undergone conformity assessment at the time of manufacture, it is evident that only non-destructive methods can be applied [4, 5].

A particularly complex task consisted in the study, identification, and establishment of a minimum set of methods capable of ensuring the safety and quality of medical devices by verifying general safety, electrical safety, and performance parameters, taking into account all the aforementioned aspects [6–9].

Accordingly, the methods selected from the standards applicable to medical devices at the manufacturing stage were incorporated into the specific procedures for periodic verification, which derive from the general procedure for periodic verification. These must correspond to the needs of the healthcare system, ensuring compliance with safety and performance parameters of medical devices, while also taking into account technological developments and international best practices in the field.

2. Phasing of the periodic verification process

Were studied standards for all 29 types of medical devices, in accordance with the Nomenclature approved by the Annex to Government Decision No. 966/2017 "On the approval of the Regulation regarding the periodic verification of medical devices placed into service and in use", for the purpose of developing and approving specific procedures for periodic verification.

As an example, in order to determine the methodology for developing a specific procedure for periodic verification, was selected, the electrocardiograph.

The development of a specific procedure for periodic verification was based on several stages, namely:

At the first stage, harmonized European standards adopted as Moldovan standards concerning general safety, electrical safety, and performance requirements were analyzed and selected. For example, for electrocardiographs: *Standard SM EN 60601-1-8, SM EN 60601-1-8/A1/AC "Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems"* [10]; *Standard SM EN 62353 "Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment"; Standard SM SR EN 60601-1 "General requirements for basic safety and essential performance"* [11]*; Standard SM EN 60601-2-25 "Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs"* [12]*; Standard SM EN 60601-2-51 "Medical electrical equipment – Part 2-51: Particular requirements for safety, including essential performance, of recording and analyzing single-channel and multi-channel electrocardiographs"* [13]; *Standard SM EN 60601-2-47 "Medical electrical equipment – Part 2-47: Particular requirements for safety, including essential performance, of ambulatory electrocardiographic systems"* [14].

Subsequently, the terminology and definitions used were examined and studied in order to ensure the correct interpretation of the specific procedure for periodic verification, in accordance with the regulatory framework in the field of medical devices. At the same time, it has been established that, in order to perform periodic verification of all types of medical devices, the following are required: *medical device testers, simulators, connection cables, measuring instruments (multimeters), as well as computers equipped with software for data acquisition and processing* [15].

Furthermore, in accordance with standard provisions, prior to initiating periodic verification, environmental conditions must be confirmed, specifically: *ambient temperature between (15–35) °C and relative humidity between (45–75) %* [15].

Another mandatory condition is that only specialists who have undergone safety training and are familiar with the operating documentation of the medical device are allowed to perform the verification.

Subsequently, for the same type of medical device, taking as an example: the electrocardiograph, all non-destructive methods specified in the standards were studied and analyzed in order to establish a minimum set of methods capable to ensure the performance and safety parameters.

Accordingly, the identification and analysis of methods from the standards were carried out in stages, namely:

- ✓ methods related to general safety;
- ✓ methods related to electrical safety;
- ✓ methods related to device performance.

After preparing the medical device for periodic verification through examination and testing, as described above, before verifying electrical safety and performance parameters, the device must first be tested for general safety.

Thus, according to standard SM SR EN 60601-1, from the perspective of general safety for electrocardiographs, the following methods requiring examination and testing were identified:

- ✓ classification of medical devices;
- ✓ instability during transport;
- ✓ interruption of power supply/mains supply to the medical device;

- ✓ mains-connected parts, components, and their arrangement;
- ✓ legibility of markings;
- ✓ marking on the exterior and interior of the device or applied parts [10–14].

Specific to electrocardiographs, for conformity control based on the requirements of standards SMV EN 60601-1-1 and SMV EN ISO 9919, methods for visual inspection and functional testing were established as necessary, namely:

Visual inspection:

- ✓ intact housing (no missing components);
- ✓ intact connectors;
- ✓ intact buttons;
- ✓ intact display;
- ✓ sensor condition;
- ✓ interconnection cable condition.

Functional verification:

- ✓ display brightness;
- ✓ self-test functionality;
- ✓ functional buttons;
- ✓ presence of alarm sound;
- ✓ presence of battery;
- ✓ detection of missing sensor or interconnection cable [10–14].

Requirements regarding the verification of sealing and marking elements related to the device housing and connection cables were studied and subsequently selected.

For the periodic verification of electrical safety parameters of the electrocardiograph, Standard SM SR EN 60601-1 was studied, and essential methods related to electrical operation were selected. Accordingly, for electrically powered medical devices, including electrocardiographs, the following methods are relevant:

- ✓ measurement of supply voltage;
- ✓ power consumption;
- ✓ earth leakage currents;
- ✓ patient leakage currents;
- ✓ enclosure leakage currents;
- ✓ auxiliary leakage currents;
- ✓ insulation resistance [10–14].

Furthermore, according to Standard SMV EN 60601-2-51, specific to electrocardiographs, several methods for periodic verification related to performance parameters were studied and identified, for example:

- ✓ requirements for amplitude measurement;
- ✓ requirements for waveform interval and duration;
- ✓ requirements for stability under noise conditions;
- ✓ minimum configuration requirements;
- ✓ calibration signal;
- ✓ sensitivity accuracy;
- ✓ internal filters;
- ✓ noise level;
- ✓ high-frequency response;
- ✓ low-frequency response;

- ✓ recording speed [10–14].

Using the methodology described above, periodic verification methods were identified and established from the standards applicable to electrocardiographs. Similarly, standards for all types of medical devices included in the approved Nomenclature were studied in order to develop specific procedures for periodic verification.

3. Measurement of the time required for periodic verification

In accordance with the stages of the general procedure for periodic verification, the time required for electrocardiograph verification was measured and estimated, as presented in Table 1.

Table 1

Time required for the periodic verification of the electrocardiograph

Nr. d/o	**Title of the works related to periodic verification**		**Time** (hours)
1.	**Receipt and analysis of the request for performing periodic verifications**		**0,10**
	1.1	registration of the testing request	0,05
	1.2	preparation of test and examination sheets for recording results	0,05
2.	**Preparation of the medical device for testing**		**0,05**
3.	**Performing examinations and testing of parameters**		**2,20**
	3.1	general safety parameters	0,15
	3.2	of the alarm system	0,00
	3.3	electrical safety	0,55
	3.4	performance	1,10
4.	**Preparation of the inspection report**		**0,20**
	5.1	transfer of data from the test sheet and completion of the report	0,15
	5.2	conclusions and remarks on the medical device	0,05
5.	**Issuance of the inspection certificate based on the report**		**0,10**
Total			**3,05**

Accordingly, the time required for the periodic verification of the electrocardiograph is approximately 3.05 hours.

Similarly, the time required to perform periodic verification was measured and estimated for another 8 types of medical devices from the Nomenclature, namely:

patient monitor;
pulse oximeter;
infusion pump;
artificial ventilation device (ventilator);
external defibrillation device (defibrillator);
electrosurgical unit (electro coagulator);
neonatal incubator;
neonatal resuscitation table.

The time required for periodic verification consists of the totality of activities aimed at evaluating general safety parameters, alarm system parameters, electrical safety, and performance.

At the same time, it was observed that the time required to verify electrical safety parameters is approximately the same for electrically powered medical devices. Similarly, the time required to verify general safety parameters is nearly identical across all types of medical devices. The difference is mainly determined by the time required to assess performance parameters (Figure 1).

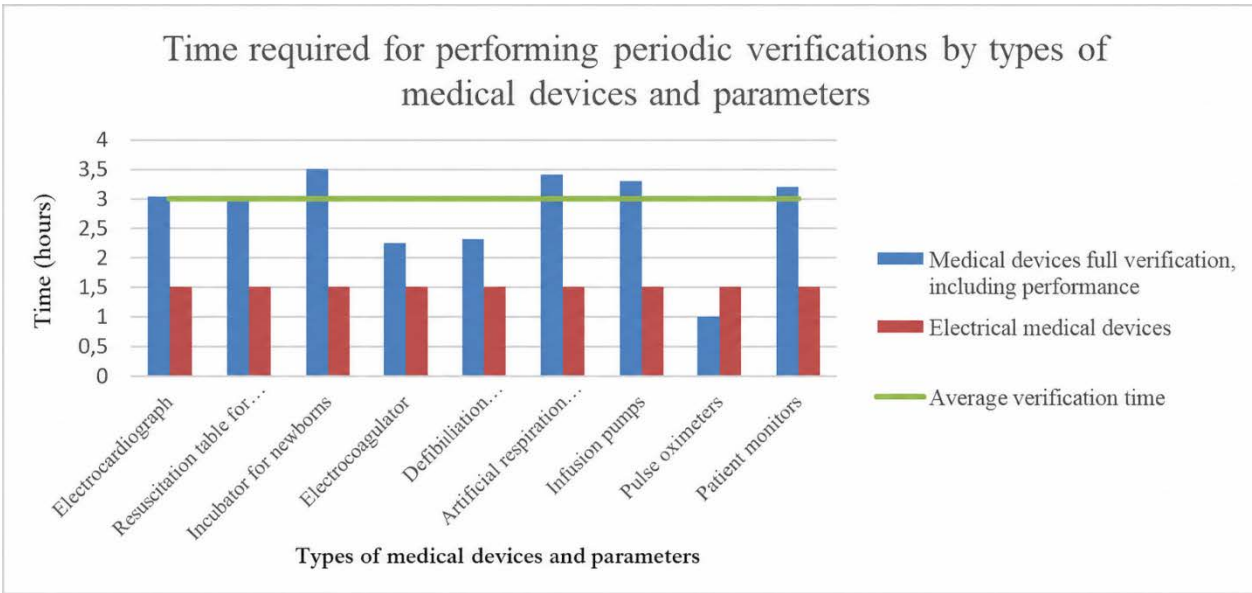

Figure 1. Time required for performing periodic verifications by types of medical devices and parameters.

Furthermore, based on the 9 types of medical devices selected for estimating the verification time, representing approximately one-third of the total number of device types in the Nomenclature, the total time required for the periodic verification of the entire inventory of medical devices was estimated.

Based on the calculated data, it was determined that the average time required for the periodic verification of a single medical device is approximately 3 hours (Figure 1). This represents a considerable amount of time, implying higher costs for medical institutions, given the hourly labor cost associated with periodic verification services.

At the same time, the measured average time of approximately 3 hours indicates a prolonged downtime of medical devices during the verification process.

4. Optimization of the time required for the periodic verification

In the context of the estimated time of approximately 3 hours for the periodic verification of medical devices, which was found to be quite high, it became necessary to review and reduce this duration, but not at the expense of confirming the conformity of device parameters. This required determining the minimum set of methods for periodic verification of general safety, electrical safety, and performance parameters.

To obtain a clearer overview of all medical devices subject to periodic verification, information was extracted from the Medical Devices Management Information System (SIMDM) regarding the units of medical devices available in medical institutions for the 9 selected types [7].

Based on the number of medical devices, the total time required for their periodic verification was estimated, as shown in Table 2.

Table 2

Estimation of the total time required for the periodic verification of medical devices according to the units extracted from SIMDM

Nr. d/o	**Name of the type of medical device**	**Quantity** (units)	**Time required for the periodic verification of a medical device** (hours)	**Time required for the periodic verification of all medical devices** (hours)
1.	Electrocardiographs	2678	3,05	8167
2.	Neonatal resuscitation tables	123	3,00	369
3.	Neonatal Incubators	202	3,50	707
4.	Electrosurgical units (electro coagulators)	376	2,25	846
5.	Defibrillation resuscitation devices	799	2,30	1837
6.	Artificial ventilation devices	1468	3,40	4991
7.	Infusion pumps	3091	3,30	10200
8.	Pulse oximeters	1618	1,00	1618
9.	Patient monitors	2226	3,20	7123
10.	Electrically powered medical devices	50000	1,50	75000

The calculation of the total time required for the periodic verification of all medical devices at the national level indicates that approximately 75,000 hours would be needed, equivalent to 3,125 days of 24 hours each. Considering standard 8-hour working days in accordance with the Labor Code of the Republic of Moldova, and the fact that a maximum of 2,000 working hours per year is estimated, the periodic verification of 9 types of medical devices at the national level (*including electrically powered devices*) would require 9,375 working days, that is, over 26 years.

It should also be noted that the lifespan of a medical device varies between 5 and 10 years, and only rarely reaches 15 years, during which the device must remain safe, effective, and of high quality. Therefore, the evaluation of performance and safety must be ensured within the device's lifespan, which further emphasizes the need to optimize verification time.

For further analysis, the same type of medical device, the electrocardiograph, was used. Thus, the periodic verification of all electrocardiographs at the national level would require 8,167 hours, equivalent to more than 4.2 working years, a very long duration that necessitated identifying solutions to reduce this timeframe.

The viable solution consisted in reviewing the number of methods identified from standards and establishing a minimum set of methods for verifying general safety, electrical safety, and performance parameters.

In this regard, a working group within the Ministry of Health (*including representatives from the Ministry of Health, the Medicines and Medical Devices Agency, the Technical University of Moldova, the Conformity Assessment Bodies as well as biomedical engineers and other specialists*) aimed to establish the minimum set of methods for periodic verification [6].

Accordingly, the verification time was measured and estimated in such a way as to allow the confirmation of device conformity within its operational lifespan, thereby ensuring the provision of safe, effective, and high-quality medical devices within the healthcare system.

As a result, for the electrocardiograph, out of 12 performance parameter methods, 5 methods were selected.

Similarly, the minimum set of methods was established for each type of medical device, forming the basis for the development of specific procedures for periodic verification, which were subsequently approved by Order of the Ministry of Health. Thus, based on the established methods, a draft Order was developed for the approval of 29 specific procedures for the periodic verification of medical devices put into service and in use [2, 3].

Following the development of this draft, the Order of the Ministry of Health, Labor and Social Protection No. 30 of January 12, 2018 was approved, which endorses the specific procedures for periodic verification of medical devices, and was published in the Official Gazette on February 23, 2018.

With the approval of these procedures, it can be stated that a new system for periodic verification has been successfully created and implemented, representing an important step for the healthcare system of the Republic of Moldova. Currently, the regulatory framework is fully applicable, enabling periodic verification of medical devices at the national level.

5. Conclusions

The development of periodic verification methods for medical devices is based on the requirements set out in the standards applicable at the manufacturing stage.

The approval of specific procedures for periodic verification represented the final stage in the creation and implementation of the new system for periodic verification of medical devices in the Republic of Moldova.

With the approval of these procedures, it can be firmly stated that the new system for periodic verification of medical devices has been fully established, representing an essential and highly significant step for the national healthcare system. The conformity assessment of medical devices, through which compliance with safety and performance parameters is confirmed, contributes to increasing the safety and quality of medical services within the healthcare system.

Currently, the entire regulatory framework governing periodic verification of medical devices has been approved, and the mechanism is functional and applicable to all public healthcare institutions in the country.

All medical institutions in the country (approximately 400) are required to ensure the periodic verification of medical devices for 29 types, in accordance with the nomenclature and mechanism approved by Government Decision No. 966/2017 on the approval of the Regulation concerning the periodic verification of medical devices that have been put into service and are in use.

Based on the results obtained, the following recommendation can be formulated:

The new system for periodic conformity assessment of medical devices has been successfully implemented at the national level. At the same time, the list of medical devices

subject to mandatory periodic verification may be expanded in order to cover a broader range of medical devices used within the healthcare system of the Republic of Moldova.

Acknowledgments The study was supported by the State Program LIFETECH "Innovations in Biomedical Engineering: Advanced Technologies and Applications for Data Acquisition, Processing and Analysis" No. 020404 at Technical University of Moldova.

Conflict of interest: I declare the absence of a conflict of interest.

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Citation: Gorceag, Gh., Lupan, O., Railean, S., Ababii, N. (2026). Optimization of the conformity assessment process for medical devices under conditions ensuring the evaluation of safety and performance parameters. *Journal of Engineering Science*. 2026, 33 (2), pp. 61-70. https://doi.org/10.52326/jes.utm.2026.33(2).05.

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